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Children as donors: a national study to assess procurement of organs and tissues in pediatric intensive care units

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Summary

A shortage of size-matched organs and tissues is the key factor limiting transplantation in children. Empirical data on procurement from pediatric donors is sparse. This study investigated donor identification, parental consent, and effectuation rates, as well as adherence to the national protocol. A national retrospective cohort study was conducted in all eight Dutch pediatric intensive care units. Records of deceased children were analyzed by an independent donation officer. Seventy-four (11%) of 683 deceased children were found to be suitable for organ donation and 132 (19%) for tissue donation. Sixty-two (84%) potential organ donors had been correctly identified; the parental consent and effectuation rate was 42%. Sixty-three (48%) potential tissue donors had been correctly identified; the parental consent and effectuation rate was 27%. Correct identification increased with age (logistic regression, organs: $P = .024$; tissues: $P = .011$). Although an overall identification rate of 84% of potential organ donors may seem acceptable, the variation observed suggests room for improvement, as does the overall low rate of identification of pediatric tissue donors. Efforts to address the shortage of organs and tissues for transplantation in children should focus on identifying potential donors and on the reasons why parents do not consent.

Introduction

There is a growing worldwide shortage of organs and tissues for transplantation, especially for children, who often need size-matched organs and tissues and have a high risk of dying while on the waiting list [1,2].

In view of the shortage of organs and tissues, one would expect the pediatric procurement process to have been scrutinized and optimized, and barriers to donation lowered. Barriers, however, still exist, and include failure to identify potential donors and to notify the organ procurement organizations, failure to discuss donation with families, and cultural barriers between potential donor families and medical staff [3]. The authors who identified these barriers suggest that an increased focus on identifying potential donors and improving consent processes is needed in all hospitals [3]. Data about the process of organ procurement in pediatrics, however, are sparse, as are data about pediatric tissue procurement [4]. To date, no empirical studies have addressed the identification of potential pediatric donors by medical professionals. Parental consent rates for donation were found by Tsai *et al.* and Webster *et al.* to be 63% and 69%, respectively, in North American brain-dead children [5,6]. Extracting data from the United Kingdom's Potential Donor Audit (2006–2007), Brierley found a 58% parental consent rate in brain-dead children [7]. None of these studies addressed the quality of the process that led to the diagnosis of "brain death."

Pediatric donation is a complex chain of events and we hypothesized that several steps of the pediatric procurement process could be improved.

Patients and methods

We performed a nationwide retrospective cohort study of all children (aged 0–17 years) who died in a Dutch Pediatric Intensive Care Unit (PICU) between January 1, 2003, and December 31, 2006, to explore:

1 How many of the children were potential organ or tissue donors;
2 How many of the children were identified as potential organ or tissue donors by the medical professional;
3 How often donation was an option offered to the parents; and
4 How many donations were actually effectuated.

To identify deceased patients, we queried both the individual hospitals' databases and the national Pediatric Intensive Care Evaluation (PICE) database. Demographic data and PICU admission data were retrieved from the hospital databases. The deceased patients' medical records were then analyzed by an investigator with extensive PICU experience. The analysis followed the protocol of the Dutch Organ Donation Act and included the investigator's and the attending medical doctor's (MD) assessment of the deceased patient's suitability as organ and/or tissue donor, and whether the MD had discussed donation with the parents. The attending medical doctors were pediatric critical care specialists. (For the different steps, see Table 1 Donation procedure in the Netherlands).

We explored the associations of donor identification with age, gender, cause of death, and hospital. As a quality check, a random sample of 10% of the medical records in three PICUs was also analyzed by an independent clinical research coordinator with extensive PICU experience. There was 100% agreement between the two assessors.

We used the following definitions, all set out in the Dutch Organ Donation Act and the national donation protocol. A patient was considered a potential organ and/or tissue donor when he or she fulfilled all medical criteria. These criteria differ for heart-beating donation, donation after cardiac death, and tissue donation. A potential heart-beating (HB) organ donor was any patient who had been declared neurologically dead by a certified neurologist or neurosurgeon, who had no contraindication (see Table 2 Absolute contraindications) against organ donation, and whose age exceeded the minimum age for the organ(s) involved. There is no minimum age for kidney or heart donation, the minimum age for liver donation is 1 month, and the minimum age for lung, pancreas, and small intestine donation is 5 years. A potential organ donation after cardiac death (DCD) donor was any patient at least 5 years old who had died within 2 h after life support had been withdrawn and who had no contraindications against organ donation. A potential tissue donor was any patient who had died and had no contraindications against tissue donation. In the Netherlands, there is no minimum age for heart valve donation; the minimum age for cornea donation is 2 years and the minimum age for bone donation is 17. In addition to absolute contraindications, there are relative contraindications, for example, proven sepsis.

Although not the focus of this study, we also obtained the identification and consent rates for the various PICUs. Finally, we assessed the MD's adherence to the national protocol and to the Dutch Organ Donation Act which both stipulate consultation of the Dutch Donor Register for every medically suitable donor aged 12 years and older [8,9]. According to Dutch legislation, children between 12 and 16 years old may register their own will as to donation and thus decide for themselves. Their parents may still overrule a wish to donate. Adulthood is ascribed at 16 years of age. However, usually PICU patients are sedated on a ventilator and, because most of the time the child's views about donation are unknown, the parents become the decision-makers.

The data were analyzed with SPSS 17 (SPSS Inc., Chicago, IL, USA). The independent sample's *t*-test was applied to test differences in age between identified and nonidentified donors. The univariate logistic regression analysis was applied to examine the association between identification and age (in years). The effects of gender and cause of death on the donation process were analyzed with chi-squared tests. A *P*-value less than .05 was considered statistically significant.

The study complied with national regulations concerning privacy and medical research. According to Dutch law,

Table 1. Donation procedure in the Netherlands.

Procedure in the Netherlands
Identify a potential donor
Check medical suitability
Check age criteria
Consult the Donor Register (12 years and older)
Make a donation request to the parents
Introduce the transplant coordinator (or organ procurement officer)

Table 2. Absolute contraindications against donation.

Absolute contraindications
Unknown cause of death
Unknown identity
Malignancy (except primary brain tumor)
Active viral infections
Active tuberculosis
Anencephaly

a survey study like this one does not require approval by a medical ethical review board. This was confirmed for the present study by the Medical Ethical Review Board of the University Medical Center Groningen.

Results

PICU characteristics

The eight Dutch PICUs were all part of tertiary referral university medical centers; they varied in size from 8 to 28 beds and admitted from 300 to 1300 patients per year. Of the 18,092 children admitted to these PICUs during the study period, 799 (4.4%) children had died [10]. One hundred and sixteen records could not be analyzed because they had become unreadable during the process of digital archiving ($N = 32$), had been miscoded ($N = 14$), or were incomplete or missing ($N = 70$), thus leaving 683 medical records suitable for analysis.

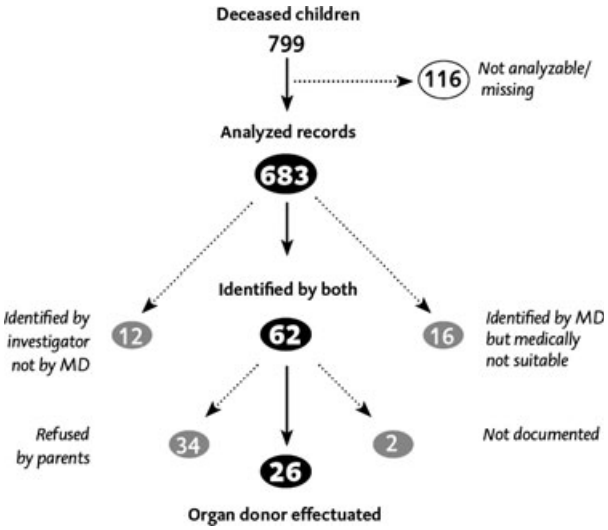

Figure 1 Identification of potential organ donors by the medical doctor (MD) and the investigator. Solid arrows show the route from death to effectuation of donation.

Patient characteristics

Of the children who died in the PICU, 44% were girls and 56% were boys. Forty-eight percent were under the age of one and 74% were less than 5 years old. Admission to the PICU was mostly nonelective (95%). Discharge diagnoses were categorized as follows: cardiovascular diseases including cardiovascular surgery (21%), respiratory insufficiency (16%), neurological diseases (18%), trauma (7%), and other causes (38%).

Organ donation

The results are summarized in Fig. 1 and Table 3. The investigator considered 609 children (89%) unsuitable for organ donation (HB or DCD), including 27 children whose medical records apparently were complete but did not contain enough information for the investigator to assess suitability for organ and tissue donation (4%). According to the MD, 605 patients (89%) were unsuitable for organ donation.

Sixty-two children (mean age 7.3 years) were considered potential organ donors by both the investigator and the MD. Another sixteen children were identified by the MD but deemed medically unsuitable upon closer assessment by the local transplant coordinator; our investigator agreed with that assessment. Twelve children (mean age 3.2 years) were identified by the investigator but not by the MD. Three of these children had died of unnatural causes (i.e., accident or drowning), while one patient had not been considered because he did not have Dutch nationality. Two patients died after withdrawal of life support and should have been considered for DCD. No reason was documented to explain why the remaining six children were not considered as potential organ donors.

Table 3. Organ donors: all pediatric deaths, suitability for donation, identification, and consent rates from all Dutch PICUs, 2003–2006.

PICU	Deceased children	Analyzable records	Suitable donors	Suitable vs. analyzable (%)	Identified by MD #	Identified vs. suitable (%)	Parental consent and effectuation #	Parental consent rate (%)
1	98	92	8	9	7	88	4	57
2	132	116	20	17	19	95	8	42
3	39	33	6	18	4	67	1	25
4	156	99	5	5	4	80	2	50
5	52	52	5	10	3	60	2	67
6	124	121	12	10	11	92	3	27
7	121	105	14	13	11	79	4	36
8	77	65	4	6	3	75	2	67
Total	799	683	74	11%	62	84%	26	42%

MD, attending physician; PICU, Pediatric Intensive Care Unit, #: absolute numbers.

In the 62 cases (84%) of correctly identified potential organ donors, the option for donation was presented to the parents. Parental consent was given in 26 cases (42%), which resulted in 26 effectuated donations: seven multi-organ donations (heart and/or lung, liver, kidney and/or pancreas), nine liver and kidney donations, and ten kidney donations. Twenty-three children were donors after neurological death and three children donated after circulatory death. In 34 cases, parents refused donation and in two cases there was no documented reason why organ donation was not effectuated.

Age differed significantly between identified and non-identified donors (independent samples *t*-test, $P = .002$). Older children were more often identified as potential organ donors by the MD than younger children (logistic regression, odds ratio 1.212, $P = .024$). Furthermore, identification was not associated with gender (χ^2, $P = .460$) or cause of death (χ^2, $P = 1.00$). Of the donations effectuated, most involved patients with trauma injuries (16 of 26 cases). We found a difference between PICUs in terms of identification rates of potential organ donors that bordered on statistical significance (χ^2, $P = .057$). There were no significant differences, however, between PICUs regarding the effectuation rates of organ donation (See Table 3).

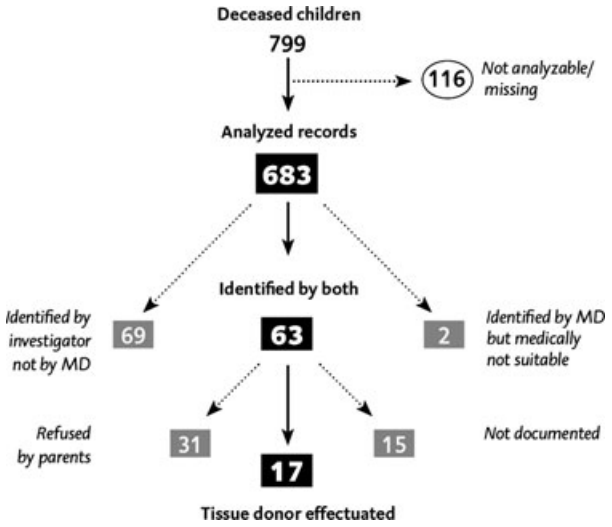

Figure 2 Identification of potential tissue donors by the medical doctor (MD) and the investigator. Solid arrows show the route from death to effectuation of donation.

Tissue donation

The results are summarized in Fig. 2 and Table 4. The investigator considered 551 children (81%) unsuitable for donating tissues, including 27 children whose medical records did not contain enough information to assess suitability (4%). According to the MD, 618 patients (90%) were unsuitable for tissue donation.

Sixty-three children (mean age 7.1 years) were considered potential tissue donors by both the investigator and the MD. Another two children were identified by the MD, but deemed medically unsuitable upon closer assessment by the local transplant coordinator; our investigator agreed with that assessment. Sixty-nine children (mean age 4.7 years) were identified by the investigator but not by the MD. Three of these children had died of unnatural causes and one patient was not considered because he did not have Dutch nationality (cf. above). For the remaining 65 children, there was no documented reason for not considering tissue donation. Fifty-one children could have donated heart valves, 16 could have donated corneas, and two could have donated both heart valves and corneas.

In the 63 correctly identified potential tissue donors (48%), the option for donation was presented to the parents. Parental consent was given in 17 cases (27%), which resulted in 17 effectuated donations: two cornea and 15 heart valve donations. Of these, eight were combined with organ donation (one cornea and seven heart valve donations). In 31 cases, parents refused donation; in 15 cases, there was no documented reason why tissue donation was not effectuated.

Table 4. Tissue donors: all pediatric deaths, suitability for donation, identification, and consent rates from all Dutch PICUs, 2003–2006.

PICU	Deceased children	Analyzable records	Suitable donors	Suitable vs. analyzable (%)	Identified by MD #	Identified vs. suitable (%)	Parental consent and effectuation #	Parental consent rate (%)
1	98	92	22	24	7	32	2	29
2	132	116	26	22	12	46	3	25
3	39	33	9	27	3	33	1	33
4	156	99	15	15	5	33	0	0
5	52	52	6	12	5	83	1	20
6	124	121	26	21	19	73	6	32
7	121	105	16	15	6	38	1	17
8	77	65	12	18	6	50	3	50
Total	799	683	132	19%	63	48%	17	27%

MD, attending physician; PICU, Pediatric Intensive Care Unit, #: absolute numbers.

Age differed significantly between identified and non-identified donors (independent samples *t*-test, $P = .010$). Older children were more often identified as potential tissue donors by the MD than younger children (logistic regression, odds ratio 1.090, $P = .011$). Identification was not associated with gender (χ^2, $P = .439$) or cause of death (χ^2, $P = .562$). Of the effectuated tissue donations, most involved patients with trauma injuries (6 of 17 cases). We found no differences between PICUs in terms of identification and effectuation rates of potential tissue donors (see Table 4).

Donor register

Consultation of the Dutch Donor Register was documented for 11 of 32 children and not documented for the other 21 children.

Discussion

This nationwide study is the first multi-center study to assess the identification process for potential pediatric donors by medical professionals. This study shows that 11% of all children who died in Dutch PICUs were potential organ donors and 19% were potential tissue donors, which compares favorably to a study of 64 Dutch hospitals in which 7–8% of adults who died in an ICU were potential organ donors [11]. On average, the MDs in this study correctly identified 84% of the potential organ donors and 48% of the potential tissue donors. Parents consented to donation and donation was effectuated in 42% (26 of 62 patients) of potential organ donors. In 27% (17 of 63 patients) of potential tissue donors, parents gave their consent and donation was effectuated.

Procurement of organs and tissues for donation is a complex chain of events and every step of the process should be optimized to avoid unnecessary loss of transplantable organs and tissues. Barriers may include societal views about donation, hospital cultures, and doctors' attitudes toward donation, as well as failure to identify potential donors and failure to adequately discuss donation and procurement with the parents. In this retrospective study, we focused on identification of potential donors and parental consent rates. We also discussed procedures and documentation, since they may serve as tools to assess doctors' knowledge and awareness of donation.

Identification of a potential donor

Although identification of 84% of potential organ donors may seem acceptable, especially in view of the retrospective study design and the lack of a gold standard for classification of potential donors, identification rates below 80%, as seen in four of the eight centers, clearly suggest room for improvement, as does the overall low rate of identification of pediatric tissue donors (48%). The primary reason for low identification rates may be that doctors working in pediatrics have poor knowledge concerning organ and tissue donation, as was recently found by Wood *et al.* [12]. We previously found that doctors may not even be aware that it is possible for infants to donate tissues [4]. Conversely, MDs identified 16 potential donors that were rejected both by the local transplantation coordinator and by our researcher. We believe these misidentifications should not be seen as failures but as inherent in a system that strives for sensitivity rather than specificity. In keeping with this philosophy, the American Medical Association suggested that the development of trigger tools to identify patients at risk of progression to brain death might be helpful, thereby also suggesting that doctors' awareness might be improved [13]. Others have made a similar implication by suggesting that guidelines or protocols might be useful tools to improve identification of potential donors [4,13,14].

A second reason for low identification rates may be that pediatric doctors believe that asking for donation puts too much of a burden on bereaved parents, as was suggested by Tsai and this would also seem to apply to DCD [5,15,16].

In our study, three of 26 organ donors (12%) became donors after circulatory death, but how often the option for DCD was presented to the parents was poorly documented. Our findings should be seen as a first rough indication of the pediatric DCD potential in the Netherlands, since donation after circulatory death is a relatively new topic that raises new questions about the identification of potential donors and about medical doctors' attitudes toward donation [15]. We and others believe that it is important to present the option of DCD to families [17].

As far as we know, this study is the first to assess the identification of children as potential tissue donors and the effectuation of tissue donation by children. We found a low identification rate for potential tissue donors. As suggested earlier, we think that doctors have poor knowledge concerning the possibility of tissue donation. In our experience, doctors in pediatrics are also often unaware of the need for pediatric tissue donation. Moreover, both the lay press and the professional literature tend to pay much more attention to organ donation.

Although not the focus of this study, we found differences between PICUs (Tables 3 and 4). PICUs with the lowest number of deceased children tended to have the lowest identification rates for organ donation.

This once again stresses the importance of doctors' attitudes, awareness, and knowledge [16], which may also explain the association between identification of a potential donor and the age of the child. We speculate that doctors may feel uncomfortable asking for donation when a child is particularly young, which might end up being miscoded as nonidentification; this could be avoided.

Parental consent rate

The parental consent rates in our nationwide study were 42% for organ donation and 27% for tissue donation. These are lower than the consent rates of 58 to 69% for organ donation previously reported in two single-center [5,18] and one Organ Procurement Organization (OPO) study in North American PICUs [6], and in one study of brain-dead pediatric donors in the United Kingdom [7], but are similar to the consent rates found for adults in the Netherlands [19]. Again, our findings suggest room for improvement; as parents of pediatric donors are thought to be much more willing to agree to donation than are families of adult patients [20].

The lack of parental consent appears to be a major obstacle. Medical professionals' attitudes, local culture, and procedures are thought to be relevant factors in determining whether parents consent to donation [5,21]. The observation that both the identification rate and the parental consent rate for tissue donation were poor when compared with organ donation suggests the detrimental effect of medical professionals' lack of pertinent knowledge in terms of the quality of the donation discussion with the parents [12,18]. The retrospective study design did not allow for an in-depth analysis of the quality of the donation discussion. Rodrigue *et al.* state that parents are more likely to agree to organ donation when it is a member of the healthcare team who first raises the possibility of donation [21]. Webster *et al.* suggest a close collaboration between pediatric intensivist and OPO [6]. The American Academy of Pediatrics recommends the use of local OPOs or hospital staff specifically trained in organ procurement [22]. In the Netherlands, it is usually the medical doctor who discusses donation with the parents, preferably the pediatric intensivist who has the closest professional bond with the parents. The medical doctor often consults with a hospital staff member specifically trained in organ procurement. Further study is needed to better comprehend the impact of this and other approaches, and to improve this important step.

Procedures and documentation

Accurate documentation, as prescribed by law, is a prerequisite for accountability to the next of kin and to society, and is of paramount importance in analyzing the procurement process. We were taken aback to find that the obligatory consultation of the Dutch Donor Register had been made in only 34% of patients who were 12 years and older. This is remarkable as we know that in the Netherlands children over 12 years old seem to be willing to think and decide about donation [23]. The Donor Register was consulted in 92% of cases with Dutch adult patients [11]. We do not imply that our findings signify any doctor's indifference or negligence, but we do interpret these findings as a sign that in general the knowledge and awareness of the donation protocol of all doctors may need to be improved.

Study limitations

We are aware that our study has several limitations. Any retrospective study may result in interpretation bias and suffer from missing data. Although a structured model was used, it is conceivable that the MD assessed an individual's donation potential correctly and that we, by having to rely on the medical records, assessed the potential incorrectly. The retrospective design allowed us to assess donor identification, consent, and effectuation rates, but made our study less robust with regard to learning why patients were not identified or why consent was not obtained. A prospective study is needed to gain insight into these questions and to assess and address possible differences between centers. The study period comprised the years 2003 through 2006. Since then, donation by adults has repeatedly been the subject of national debate and publicity campaigns in the Netherlands. However, pediatric donation, at least in the Netherlands, remains a very delicate subject that is rarely if ever discussed in public. Whether pediatric donation has benefited from the publicity concerning adult donation remains to be seen. Moreover, the results of our study should be translated to other countries and cultures with care. That said, our study may serve as a baseline for future comparisons and studies, and it supports the notion that, in spite of all the efforts made so far, the process of organ and tissue procurement in pediatrics can still and should be improved.

Further studies of the procurement process are needed to improve our understanding about donation decisions. We believe further education of the professional staff about donation in pediatrics, as well as active sharing of knowledge and experience, may help improve the procurement process. Active steps that might be taken could include the development of national pediatric (online) donation guidelines and a systematic prospective assessment of PICU deaths.

Conclusions

Efforts to address the shortage of organs and tissues for transplantation in children should focus on the identification of potential donors and the reasons why parents do not consent to donation. We suggest that future studies address these important steps in the procurement process. Differences between hospitals' identification and consent rates, and failure to consult the Dutch Donor Register (or document the consultation), may serve as tools to identify gaps in the knowledge, attitudes, and skills of professional staff.

Authorship

M.J.S.: designed and conducted the research, collected and analyzed the data, wrote the paper. M.J.I.J.A: designed research, analyzed the data and contributed important reagents. P.F.R.: contributed important reagents. H.B.M.V.dW: contributed important reagents.

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